

Art Unit: \*\*\*

CLMPTO

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AC

1. Implant comprising or consisting of titanium  
5 and having one or more surfaces which can be applied in  
or on tissue areas and/or bone growth areas, one or  
more of the said surfaces being arranged with a depot  
for bone-growth-initiating or bone-growth-stimulating  
10 substance, which depot is formed by a pore arrangement  
in a relatively thick oxide layer on the titanium,  
characterized in that the substance, for a period of  
time, is acted on by, or works with, one or more  
release functions which permit a preferably essentially  
15 controlled release of substance to the respective  
surrounding tissue or tissue/bone growth areas.

2. Implant according to Patent Claim 1,  
characterized in that two or more release arrangements  
are obtained by means of different pore arrangements  
within one or more areas of one or more of the said  
20 surfaces.

3. (Amended) Implant according to Patent Claim 1, characterized in that  
pores with different pore characteristics, for example open or more or less closed  
pores, pore depth, pore density, pore volume, etc., are arranged within one or more  
areas.

4. (Amended) Implant according to Patent Claim 1, characterized in that  
the release function(s) operate(s) with combinations of larger and smaller pores  
arranged to effect a desired release sequence over time.

Art Unit: \*\*\*

5. Implant according to Patent Claim 4, characterized in that larger pores effect a more rapid release, and smaller and/or deep pores effect a delayed release.

6. (Amended) Implant according to Claim 1, characterized in that different areas are provided with different pore characteristics.

7. (Amended) Implant according to Claim 1, characterized in that the surface of the oxide layer comprises about 20% titanium, about 55% oxygen and about 20% carbon, and the layer otherwise consists of titanium dioxide.

8. (Amended) Implant according to Claim 1, characterized in that the oxide layer has a surface roughness of about 1 - 5  $\mu\text{m}$  or less.

9. (Amended) Implant according to Claim 1, characterized in that the oxide layer has a thickness in the range of 1 - 20  $\mu\text{m}$ , preferably 2 - 20  $\mu\text{m}$ .

10. (Amended) Implant according to Claim 1, characterized in that the oxide layer is highly porous, with pore diameters in the range of 0.01-10  $\mu\text{m}$ .

Art Unit: \*\*\*

15 11. Implant for application in a hole formed in  
tissue and/or bone, for example the jaw bone,  
characterized in that it comprises a titanium portion  
which can cooperate with the hole formation, in that  
the titanium portion is designed with one or more very  
20 thick titanium oxide layers having surfaces which can  
be placed against the tissue and/or bone in the hole  
formation, in that each oxide layer is provided with a  
pore arrangement which functions as a depot for bone-  
growth-initiating and/or bone-growth-stimulating  
25 substance, for example a substance belonging to the  
superfamily TGF- $\beta$ , and in that, when the depot is  
filled with substance and the implant is in position in  
the hole, a release function for releasing the  
substance to the bone comes into operation.

30 12. Implant according to Patent Claim 11,  
characterized in that the release function is  
controlled, for a chosen period of time.

13. Implant according to Patent Claim 12,  
characterized in that the release function is  
35 controlled by the choice of pore arrangement and pore  
characteristics in or on the said layer.

14. (Amended) Implant according to Claim 11, characterized in that the  
oxide layer is highly porous.

15. (Amended) Implant according to Claim 11, characterized in that it is a  
screw implant which bears the said oxide layers and surfaces on its threads.

Art Unit: \*\*\*

5 16. Method for producing an implant intended to be applied in or at a hole formed in tissue and/or bone, preferably the jaw bone, characterized in that the implant is produced, for example by means of machining, with a portion of titanium which has surfaces which can  
10 be placed against the bone and/or tissue when the implant is in position in the hole, in that the said titanium on the said surface or surfaces is subjected to anodic oxidation to an extent which gives a highly porous and relatively thick oxide layer on each surface  
15 concerned, in that bone-growth-initiating substance or bone-growth-stimulating substance, for example a substance belonging to the superfamily TGF- $\beta$ , is applied to the said porous and thick layers, for example by saturation or immersion, and in that the  
20 implant is placed in its position in the hole, resulting in the process of release of the substance to the bone being started by the release of components in the tissue and/or bone.

17. Method according to Patent Claim 16,  
25 characterized in that the implant, at the part or parts bearing the said surfaces, is provided with one or more threads, and in that the implant is screwed into the bone.

18. (Amended) Method according to Patent Claim 16, characterized in that the oxide layer is immersed in a container holding the substance.

19. Use of a highly porous and thick titanium oxide layer to which bone-growth-initiating and bone-growth-stimulating substance has been added, for example a  
35 substance belonging to the superfamily TGF- $\beta$ , characterized in that it is used on implants which can be inserted into holes in tissue and/or bone, preferably the jaw bone.

Art Unit: \*\*\*

20. Use according to Patent Claim 19, characterized in that it is used on the thread or threads of the implant and/or on the area above the thread or threads.

21. (Amended) Use according to Patent Claim 19, characterized in that it is used in holes involving soft and/or reduced bone.

22. Implant comprising or consisting of titanium and having one or more surfaces which can be applied in or on tissue areas and/or bone growth areas, one or  
10 more of the said surfaces being arranged with a depot for bone-growth-initiating or bone-growth-stimulating substance, for example a substance belonging to the superfamily TGF- $\beta$ , which depot is formed by a pore arrangement in a relatively thick oxide layer on the  
15 titanium, characterized in that the oxide layer has a thickness in the range of 1 - 20  $\mu\text{m}$ , for example 2 - 20  $\mu\text{m}$ .

23. Implant according to Patent Claim 22, characterized in that the oxide layer has a surface  
20 roughness in a range of 0.4 - 5  $\mu\text{m}$ .

24. (Amended) Implant according to Patent Claim 22, characterized in that the oxide layer is highly porous, with  $1 \times 10^7$  -  $1 \times 10^{10}$  pores/ $\text{cm}^2$ .

25. (Amended) Implant according to Patent Claim 22, characterized in that each surface essentially has pores with diameter sizes in the range of 0.1 - 10  $\mu\text{m}$ , and/or in that the total pore volume is within a range of  $5 \times 10^{-2}$  and  $10^{-5}$   $\text{cm}^3$ .

Art Unit: \*\*\*

26. Method for producing, on an implant comprising  
30 or consisting of titanium, and by means of anodic  
oxidation, relatively thick oxide layers on one or more  
titanium surfaces which are intended to be placed  
against or arranged adjacent to one or more tissue  
and/or bone growth areas, in which method at least the  
35 part or parts bearing the said surface or surfaces are  
prepared and immersed in electrolyte and the implant is  
brought into contact with an electrical energy source  
above the electrolyte surface, and the oxidation  
process is established by also connecting to the energy

source a counter-electrode which is arranged in the  
electrolyte, characterized in that diluted inorganic  
acids, diluted organic acids and/or small quantities of  
hydrofluoric acid or hydrogen peroxide are added to the  
5 electrolytic composition, and in that the energy source  
is chosen to operate at a voltage value or voltage  
values in the range of 150 - 400 volts.

27. Method according to Patent Claim 26,  
characterized in that the voltage is varied for the  
10 same implant at different times in order to create  
different pore sizes within the same surface areas.

28. (Amended) Method according to Patent Claim 26, characterized in  
that the position of the implant in the electrolyte is changed, together with the  
composition of the electrolyte and/or the voltage, in order to create different oxide  
thicknesses and/or areas with different porosity or pore characteristics.